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Original Research Article

COMPARATIVE EVALUATION OF THE EFFECTS OF SILODOSIN AND TADALAFIL IN PATIENTS OF BENIGN PROSTATE HYPERPLASIA WITH LOWER URINARY TRACT SYMPTOMS

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ABSTRACT

Background: Silodosin is a highly selective alpha-1A receptor antagonist with little or no cardiovascular adverse effects. Previous immunohistochemical researches indicate that PDE5 is localized on the endothelial and smooth muscle cells of the lower urinary tract blood vessels. Various studies reported that PDE5- inhibitors can relax isolated prostate and bladder neck strips. **Material & Methods:** The present prospective observational study was conducted at the Department of surgery at our tertiary care hospital. The study duration was June 2018 to May 2019. A sample size of 150 was calculated at a 90 % confidence interval at a 5 % acceptable margin of error. Clearance from Institutional Ethics Committee was taken before the start of the study. Written informed consent was taken from each study participant. **Results**: In the silodosin group PVR improve from 63.6 ml (average) to 32.8 ml (48.42% improvement) while in the tadalafil group PVR dropped from an average of 54.2 ml to 27.9 ml (i.e. 48.53% improvement). In the silodosin group Qmax at the time of presentation was 12.9 and at 4th and 12th week was 15.4 and 17.3 respectively (25.4% improvement). Qmax in PDE5 I group improves from 13.0 to 15.6 in the 4th week and further to 17.4 in the 12th week (26% improvement). In the silodosin group, IPSS was 18.6 at the time of presentation which also improves to 14.8 and 12.8 at 1 and 3 months respectively. Thus 31.2% improvement was seen in the silodosin group. In the tadalafil group, the IPSS at the time presentation was 16.2 which improves further to 12.6 and 10.9 at 1 and 3 months respectively. Overall, 35.2% improvement was seen in the tadalafil group. In terms of p-value, there was a significant improvement in intragroup comparison at initial, 1 month, and 3 months assessment (p-value <0.05), But when compared with both groups, the improvement was not statistically significant (p-value >0.05). **Conclusion:** We concluded from the present study that the outcome of the individual drugs was compared with each other and no statistically significant advantage was observed in terms of outcome.

Keywords: BPH, IPSS, Qmax.

INTRODUCTION

Catheter-related The incidence of benign prostate hyperplasia is age-dependent with cases seen mostly after the age of 45 years **(1)**. Various studies reported that the prevalence is increased with age, by the age of 60 years its prevalence is reported more than 50%, and by the age of 85 its prevalence is reported around 90%. Benign prostate hyperplasia (BPH) is one of the most common age-related benign neoplasm among males **(2).** The hyperplasia of the stromal and epithelial cells of the prostate leads to the formation of discrete nodules around the periurethral region. These pathological changes lead

to an enlarged prostate gland and causing lower urinary tract symptoms (LUTS) in patients. Benign prostate hyperplasia is reported to be associated with decreased quality of life by affecting daily activities and sleep patterns. Various studies reported that BPH is associated with many complications such as acute urinary retention, renal function impairment, hematuria, etc **(3).**

The lower urinary tract symptoms such as poor and/or intermittent stream, prolonged micturition, straining, dribbling, feeling of incomplete bladder emptying are known as obstructive symptoms and other symptoms such as frequency, urge incontinence, urgency, and nocturia known as storage symptoms **(4)**. Various studies reported that there are both medical and surgical lines of treatments are available for benign prostate hyperplasia. Among the medical line of treatment, various therapies are used for BPH and these are based on its pathogenesis **(5)**. BHP has two approaches of medical treatment, first is to reduce the volume of the prostate gland for that 5α-reductase inhibitors are used such as finasteride and dutasteride, the second approach is to dilate the prostatic urethra for that α-blockers are used tamsulosin, alfuzosin, silodosin, terazosin and doxazosin **(6).** Silodosin is a highly selective alpha-1A receptor antagonist with little or no cardiovascular adverse effects. Previous immunohistochemical researches indicate that PDE5 is localized on the endothelial and smooth muscle cells of the lower urinary tract blood vessels. Various studies reported that PDE5- inhibitors can relax isolated prostate and bladder neck strips **(7)**. Hence the present study was conducted to comparatively evaluate the effects of Silodosin and Tadalafil in patients of benign prostate hyperplasia with lower urinary tract symptoms.at our tertiary care center.

MATERIALS & METHODS

The present prospective observational study was conducted at the Department of Surgery at our tertiary care hospital. The study duration was June 2018 to May 2019. A sample size of 150 was calculated at a 90 % confidence interval at a 5 % acceptable margin of error by epi info software version 7.2. Patients were enrolled from the outdoor department and ward by simple random sampling. Institutional Ethics Committee Clearance was obtained before the start of the study and written and informed consent for the procedure was obtained from all the patients. Strict confidentiality was maintained with patient identity and data and not revealed, at any point in time.

Study participants aged more than 45 years and diagnosed with benign prostate hyperplasia were enrolled for the study. Patients who were already on alpha-blockers, patients with recurrent episodes of LUTS, patients with haematuria, patients with chronic kidney disease, patients with bilateral hydroureteronephrosis, patients with bladder calculi, bladder diverticula were excluded from the present study. All the study participants with lower urinary tract symptoms were accessed with IPSS based questionnaire, uroflowmetry, and USG KUB with PVR **(8)**. All data of the patient was recorded on predesigned Performa. All study participants were prescribed Silodosin and Tadalafil medication randomly and advised to come for follow-up after 1 month and 3 months. On follow-up visits, the same data were recorded and compared. All the data was recorded on a Microsoft Excel spreadsheet and data analysis was done at 10% alpha and 90% confidence interval using SPSS v22 software. Test of significance was applied on collected and organized data and a p-value less than 0.05 was considered as a statistically significant association between study variables.

RESULTS

In the present study, we enrolled 150 patients diagnosed with benign prostate hyperplasia. Study participants were randomized into two equal groups, the group I consisted of patients who were given silodosin, and group II consists of patients who were given tadalafil. The average age of study participants was 60.7 ± 3.92 years with an average BMI of 25.8 kg/m2. l. In the silodosin group PVR improve from 63.6 ml (average) to 32.8 ml (48.42% improvement) while in the tadalafil group PVR drops from an average of 54.2 ml to 27.9 ml (i.e. 48.53% improvement). In terms of p-value, there was a significant improvement in intragroup comparison at initial, 1 month, and 3 months assessment (p-value <0.05), But when compared with both groups, the improvement was not statistically significant (p-value >0.05). (Table 1)

In the present study, based on Qmax assessment it was observed that among the silodosin group Qmax at the time of presentation was 12.9 and at 4th and 12th week was 15.4 and 17.3 respectively (25.4% improvement). Qmax in PDE5 I group improves

from 13.0 to 15.6 in the 4th week and further to 17.4 in the 12th week (26% improvement). In terms of p-value, there was a significant improvement in intragroup comparison at initial, 1 month, and 3 months assessment (p-value <0.05), But when compared with both groups, the improvement was not statistically significant (p-value >0.05). (Table 2).

Table 1: Distribution of study subjects according to the PVR assessment.

			Mean	SD	P value
Basal PVR		Group I	63.6	18.94	>0.05
		Group II	54.2	10.82	
At month	1	Group I	42.8	13.56	>0.05
		Group II	38.6	8.71	
At months	3	Group I	32.8	10.63	>0.05
		Group II	27.9	6.89	

Table 2: Distribution of study subjects according to the Qmax assessment.

			Mean	SD	P value
Basal Qmax		Group I	12.9	2.65	>0.05
		Group II	13.0	3.82	
At month	1	Group I	15.4	3.42	>0.05
		Group II	15.6	4.21	
At months	3	Group I	17.3	3.01	>0.05
		Group II	17.6	3.89	

Table 3: Distribution of study subjects according to the IPSS assessment.

			Mean	SD	P value
Basal IPSS		Group I	18.6	5.94	>0.05
		Group II	16.2	6.32	
At month	1	Group I	14.8	4.56	>0.05
		Group II	12.6	5.71	
At months	3	Group I	12.8	3.63	>0.05
		Group II	10.5	4.19	

In the present study, based on IPSS assessment, it was observed that among the silodosin group IPSS was 18.6 at the time of presentation which also improves to 14.8 and 12.8 at 1 and 3 months respectively. Thus 31.2% improvement was seen in the silodosin group. In the tadalafil group, the IPSS at the time of presentation was 16.2 which improves further to 12.6 and 10.9 at 1 and 3 months respectively. Overall 35.2% improvement was seen in the tadalafil group. In terms of p-value, there was a significant improvement in intragroup comparison at initial, 1 month, and 3 months assessment (p-value <0.05), But when compared with both groups, the improvement was not statistically significant (p-value >0.05). (Table 3).

DISCUSSION

In the present study, we enrolled 150 patients diagnosed with benign prostate hyperplasia. Study participants were randomized into two equal groups, the group I consisted of patients who were given silodosin, and group II consists of patients who were given tadalafil. The average age of study participants was 60.7 ± 3.92 years with an average BMI of 25.8 kg/m2. l. In the silodosin group PVR improve from 63.6 ml (average) to 32.8 ml (48.42% improvement) while in the tadalafil group PVR drops from an average of 54.2 ml to 27.9 ml (i.e. 48.53% improvement). In terms of p-value, there was a significant improvement in intragroup comparison at initial, 1 month, and 3 months assessment (p-value <0.05), But when compared with both groups, the improvement was not statistically significant (p-value >0.05). Similar results were obtained in a study conducted by Singh SN et al among 54 patients with benign prostate hyperplasia and found similar findings to the present study. They randomized study participants among the alpha-blockers group, PDE5 1 group, and combination of both drugs groups **(9)**.

In the present study, based on Qmax assessment it was observed that among the silodosin group Qmax at the time of presentation was 12.9 and at 4th and 12th week was 15.4 and 17.3 respectively (25.4% improvement). Qmax in PDE5 I group improves from 13.0 to 15.6 in the 4th week and further to 17.4 in the 12th week (26% improvement). In terms of p-value, there was a significant improvement in intragroup comparison at initial, 1 month, and 3 months assessment (p-value <0.05), But when compared with both groups, the improvement was not statistically significant (p-value >0.05). Similar results were obtained in a study conducted by J Y Lee et al among 158 patients with benign prostate hyperplasia and found similar findings to the present study **(10)**. Similar results were obtained in a study conducted by Sing DV et al among 133 patients with benign prostate hyperplasia and found similar findings to the present study **(11).**

In the present study, based on IPSS assessment it was observed that among the silodosin group IPSS was 18.6 at the time of presentation which also improves to 14.8 and 12.8 at 1 and 3 months respectively. Thus 31.2% improvement was seen in the silodosin group. In the tadalafil group, the IPSS at the time presentation was 16.2 which improves further to 12.6 and 10.9 at 1 and 3 months respectively. Overall, 35.2% improvement was seen in the tadalafil group. In terms of p-value, there was a significant improvement in intragroup comparison at initial, 1 month, and 3 months assessment (p-value <0.05), But when compared with both groups, the improvement was not statistically significant (p-value >0.05). Similar results were obtained in a study conducted by Takashi Y et al among 103 patients with benign prostate hyperplasia and found similar findings to the present study **(12)**. Similar results were obtained in a study conducted by Wang XH et al among patients with benign prostate hyperplasia and found similar findings to the present study. They conducted a systematic review and meta-analysis on α-adrenoceptor antagonists and phosphodiesterase 5 inhibitors used alone or in combination for the treatment of LUTS due to benign prostate hyperplasia **(13)**.

CONCLUSION

We concluded from the present study that the outcome of the individual drugs was compared with each other and no statistically significant (p-value >0.05) advantage was observed in terms of outcome. However, the result of the present study cannot be generalized due to the small sample size. Further studies with a larger sample size and long duration of follow up are needed.

REFERENCES

1. Benign prostatic hyperplasia (BPH): symptoms, diagnosis & treatment. Urology Care Foundation [Internet]. Available from: https://www.urologyhealth.org/urologic-conditions/benign-prostatic-hyperplasia-(bph).

2. Roehrborn CG. Benign prostatic hyperplasia: an overview. Rev Urol. 2005;7;Suppl 9 [Suppl:S3-S14]:S3-S14. PMID 16985902.

3. Lee CL, Kuo HC. Pathophysiology of benign prostate enlargement and lower urinary tract symptoms: current concepts [internet]. Tzu Chi Med J. 2017;29(2):79-83. doi: 10.4103/tcmj.tcmj_20_17, PMID 28757771. Available from: /pmc/articles/PMC5509197/?report=abstract.

4. Lu SH, Chen CS. Natural history and epidemiology of benign prostatic hyperplasia. Formos J Surg. 2014;47(6):207-10. doi: 10.1016/j.fjs.2014.10.001.

5. Bruskewitz RC. Quality of life and sexual function in patients with benign prostatic hyperplasia. Rev Urol. 2003;5(2):72-80. PMID 16985624.

6. Muruganandham K, Dubey D, Kapoor R. Acute urinary retention in benign prostatic hyperplasia: risk factors and current management. Indian J Urol. 2007 Oct 1;23(4):347-53. doi: 10.4103/0970-1591.35050, PMID 19718286. Available from: /pmc/articles/PMC2721562/?report=abstract.

7. Brock G, Broderick G, Roehrborn CG, Xu L, Wong D, Viktrup L. Tadalafil once daily in the treatment of lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) in men without erectile dysfunction. B.J.U. Int. 2013 Nov;112(7):990-7. doi: 10.1111/bju.12251, PMID 23937669.

8. International consultation on benign prostatic hyperplasia. Available from: https://apps.who.int/iris/handle/10665/41818. Paris F, Cockett ATK. The international consultation on benign prostatic hyperplasia (BPH, Paris, June 26-27, 1991. Proceedings of the/editors, A.T. K. Cockett ... [et al.]. Vol. 1992; 1991.

9. Narayan Singh S, Biswas M, Mittal A, Kalra Y, Sarpal R, Agrawal S, Pal R, Chugh B. Comparing the effect of Alpha blocker (silodosin) and phosphodiesterase type 5 inhibitor (tadalafil) in benign prostate hyperplasia patients with lower urinary tract symptoms: a single centre study. Int Surg J. 2018;5(5):1866. doi: 10.18203/2349-2902.isj20181599.

10. Lee JY, Park SY, Jeong TY, Moon HS, Kim YT, Yoo TK, Choi HY, Park HY, Lee SW. Combined tadalafil and α-blocker therapy for benign prostatic hyperplasia in patients with erectile dysfunction: a multicenter, prospective study. J Androl. 2012 May;33(3):397-403. doi: 10.2164/jandrol.111.013185, PMID 21868753.

11. Singh DV, Mete UK, Mandal AK, Singh SK. A comparative randomized prospective study to evaluate efficacy and safety of combination of tamsulosin and tadalafil vs. tamsulosin or tadalafil alone in patients with lower urinary tract symptoms due to benign prostatic hyperplasia. J Sex Med. 2014;11(1):187-96. doi: 10.1111/jsm.12357, PMID 24165272.

12. Yoshida T, Kinoshita H, Shimada S, Taguchi M, Matsuda T. Comparison of silodosin monotherapy vs silodosin with tadalafil add-on therapy in patients with benign prostatic hyperplasia. Urology. 2017 Aug 1;106:153-9. doi: 10.1016/j.urology.2017.04.012, PMID 28431996.

13. Wang XH, Wang X, Shi MJ, Li S, Liu T, Zhang XH. Systematic review and meta-analysis on phosphodiesterase 5 inhibitors and α-adrenoceptor antagonists used alone or combined for treatment of LUTS due to BPH. Asian J Androl. 2015 Nov 1;17(6):1022-32. doi: 10.4103/1008-682X.154990, PMID 25994648.

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